

PART IV
USE OF X-RAY IN THE HEALTH PROFESSIONS

RHB 4.1 Scope. This part establishes requirements for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with State statutes to engage in the healing arts or veterinary medicine.

RHB 4.2 General Safety Provisions.

4.2.1 No person shall make, sell, lease, transfer, lend, repair, or install x-ray equipment or the supplies used in connection with such equipment unless such supplies or equipment, when properly placed in operation and properly used will meet the requirements of these regulations. This includes but is not limited to such items as cones, filters, adequate timers, and fluoroscopic shutters (where applicable). Also, such person shall be registered with the Department in accordance with RHB 2.5.

4.2.2 An x-ray system which does not meet the provisions of these regulations shall not be operated for diagnostic or therapeutic purposes if so directed by the Department.

4.2.3 The registrant shall assure that all X-ray machines under his control are operated only by a radiologic technologist possessing a current, valid certificate from the South Carolina Radiation Quality Standards Association, or a licensed practitioner. For the purpose of this Part, a radiologic technologist is defined as a person who is a limited practice radiographer, radiographer, podiatric limited practice radiographer or limited chest radiographer certified by the American Registry of Radiologic Technologists or who is certified by the South Carolina Radiation Quality Standards Association or who has obtained a certificate acceptable to the South Carolina Radiation Quality Standards Association. A person who applies ionizing radiation to humans or performs x-ray exam setups, including, but not limited to, patient positioning and technique selection shall be considered a radiologic technologist.

4.2.3.1 No person other than a licensed practitioner or a radiologic technologist possessing a current, valid certificate from the South Carolina Radiation Quality Standards Association shall use equipment emitting ionizing radiation on humans for diagnostic purposes.

4.2.3.2 No person shall employ or designate as a radiologic technologist a person who does not hold a current, valid certificate issued by the South Carolina Radiation Quality Standards Association.

4.2.3.3 No person holding a certificate issued by the South Carolina Radiation Quality Standards Association shall use equipment emitting ionizing radiation on humans for diagnostic purposes unless under the direction and supervision of a licensed practitioner and unless so directed by prescription of a licensed practitioner.

4.2.3.4 No person who is not certified by the South Carolina Radiation Quality Standards Association shall take, use, or exhibit the title of "limited practice radiographer", "podiatric limited practice radiographer", "limited chest radiographer", or "radiographer" or any other title, sign, display, or declaration that tends to lead the public to believe that the person is authorized to apply ionizing radiation on humans for diagnostic purposes.

4.2.3.5 A student enrolled in and attending a school or college of medicine, osteopathy, chiropractic, podiatry, radiologic technology, or a curriculum approved by the South Carolina Radiation Quality Standards Association, or a resident in an approved graduate education program of medicine, osteopathy, chiropractic, or podiatry may apply ionizing radiation to humans without a certificate from the South Carolina Radiation Quality Standards Association, as long as the student or resident is under the

supervision of a licensed practitioner or direct supervision of a certified radiologic technologist appropriately trained to supervise the specific procedure.

4.2.3.6 The registrant shall display each operator's current certificate in public view, not obstructed by any barrier, equipment, or other object.

4.2.3.7 The registrant shall ensure that each operator has received training specific to the equipment and procedures in use at his facility, including machine specific training, use of personnel monitoring devices, quality assurance procedures, and the operating procedures required by RHB 4.2.4. The registrant shall maintain a record of this training for each operator. Such records shall be made available for Departmental review.

4.2.3.8 Dentists and their auxiliaries who meet the requirements of the South Carolina Dental Practice Act are exempt from the requirements of 4.2.3.1 through 4.2.3.6.

4.2.4 The registrant shall create and make available to x-ray operators written operating procedures, including any restrictions of the operating techniques required for the proper operation of the particular x-ray system. The registrant shall adhere to the operating procedures in all respects. After initial review and approval of the procedures by the Department, any substantive changes must be submitted in writing to the Department for review and approval prior to implementation of the change. The operator shall be able to demonstrate familiarity and competence with these procedures. Documentation must be maintained, indicating that the operator has read and agrees to adhere to the operating procedures. The procedures shall include, but not be limited to:

4.2.4.1 Policies and procedures for Patient Holding;

4.2.4.2 Policies and procedures for Pregnant Workers; NRC Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure", should be used for guidance concerning pregnant workers.

4.2.4.3 Policies and procedures regarding the use of Gonadal shielding; (Registrants using x-ray equipment for veterinary purposes are exempt from this requirement.)

4.2.4.4 Policies and procedures for Pregnant patients; (Registrants using x-ray equipment for veterinary purposes are exempt from this requirement.)

4.2.4.5 Policies and procedures for Personnel Monitoring;

4.2.4.6 Procedures for training New Employees;

4.2.4.7 Methods for Quality Assurance.

4.2.5 X-ray producing machines and associated equipment shall be maintained in such a condition to ensure that the patient and staff are not exposed to radiation unnecessarily.

4.2.6 The Department may waive compliance with the specific requirements of any regulation for existing x-ray equipment or installation if:

4.2.6.1 Such compliance would require the replacement or substantial modification of the x-ray equipment or installation; and

4.2.6.2 The registrant demonstrates, to the Department's satisfaction, achievement through other means, radiation protection equivalent to that required by these regulations.

4.2.7 If an x-ray system is identified as not being in compliance with the provisions of these regulations and cannot meet the regulations, or if the registrant is unwilling to make corrections, and if that system is accessible for use, it shall be rendered inoperable (i.e. dismantle the x-ray source from the source support assembly) if so ordered by the Department.

4.2.8 In the vicinity of each diagnostic x-ray system's control panel, a chart shall be provided which specifies for all examinations performed with that system, the following information:

4.2.8.1 Patient's body part and anatomical size, or body part thickness or age (for pediatrics), versus technique factors to be used;

4.2.8.2 Type and size of the film or film-screen combination to be used;

4.2.8.3 Source to image receptor distance (SID) to be used (except for dental intra-oral radiography) and

4.2.8.4 Type and location of placement of patient shielding (e.g., gonad, thyroid, etc.) to be used.

4.2.8.5 For automatic exposure control (AEC) systems with selectable exposure detectors and density settings, the technique chart shall also specify the appropriate exposure detector(s) and density setting to be utilized for each radiographic examination listed.

4.2.8.6 For AEC systems, the technique chart shall specify the requirements of RHB 4.2.8.1 through RHB 4.2.8.4 to be followed when operated in a non-automatic mode.

4.2.8.7 The technique chart shall accurately reflect techniques currently in use at the facility.

4.2.9 A sign shall be posted in a conspicuous area so as to be easily seen by the patient to the effect that if there is a pregnancy or the possibility of a pregnancy, the physician shall be notified. Prescription of x-ray examinations of pregnant or possibly pregnant patients shall assure that medical consideration has been given to possible fetal exposure and appropriate protective measures are taken.

4.2.10 The effectiveness of protective equipment shall not be impaired. Lead aprons and gloves shall be checked at least annually for cracks and holes that could compromise the radiation protection it provides. This testing shall be documented. Records of this testing shall be kept two years, or until the next Department inspection, whichever is later.

4.2.11 Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure other than the patient being examined.

4.2.11.1 All individuals shall be positioned such that no part of the body will be struck by the useful beam, unless protected by not less than 0.5 mm lead equivalent material.

4.2.11.2 The x-ray operator, other staff, and ancillary persons shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.5 mm lead equivalent material.

4.2.11.3 When feasible, patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 mm lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

4.2.11.4 When a portion of the body of any staff or ancillary personnel is potentially subjected to stray radiation which could result in that individual receiving one quarter of the maximum permissible dose as defined in RHB 3.2 of these regulations, additional protective devices may be required by the Department.

4.2.12 Gonadal shielding of not less than 0.5 mm lead equivalent material shall be used for human patients who have not passed the reproductive age during radiographic procedures in which the gonads are in the direct beam, except in cases where the gonadal shielding would interfere with the diagnostic image desired.

4.2.13 Individuals shall not be exposed to the useful beam of electronically produced ionizing radiation except for healing arts purposes, and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

4.2.13.1 Exposure of an individual for training, demonstration or other purposes unless there are also healing arts requirements and proper prescription has been provided. Demonstrations or training on new x-ray equipment must be performed with proper protection of the observers and operator(s). Phantoms, not humans, must be used for demonstrations and training.

4.2.13.2 Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Department. When requesting such approval, that person shall submit the information outlined in Appendix A of this part. If any information submitted to the Department becomes invalid or outdated, the Department shall be notified within 15 days. Approval to conduct a healing arts screening program shall be renewed on an annual basis if deemed necessary by the Department.

4.2.14 When a patient or film must be provided with auxiliary support during a radiation exposure:

4.2.14.1 Mechanical holding devices shall be used when the technique permits. The written safety procedures required by RHB 4.2.4 shall list individual projections where holding devices cannot be used.

4.2.14.2 Written safety procedures, as required in RHB 4.2.4, shall indicate the requirements for selecting a holder, and the procedure the holder shall follow.

4.2.14.3 The human holder shall be instructed in personal radiation safety and shall be protected as required by 4.2.11.

4.2.14.4 No person shall be used routinely to hold patients or film.

4.2.14.5 In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 mm lead equivalent material.

4.2.14.6 When practical a pregnant female should not be used to hold film or patients.

4.2.14.7 Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved in x-ray operations who are not otherwise shielded. Lead aprons and gloves shall be checked at least annually for cracks and holes that could compromise the radiation protection they provide. This testing shall be documented. Records of this testing shall be kept two years, or until the next Department inspection, whichever is later.

4.2.15 Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be used.

4.2.15.1 The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging. The film cassettes shall provide good contact between the intensifying screens and the film.

4.2.15.2 The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality. Appendix D provides patient exposures that are typical of good practices. These should be used by the registrant in evaluating patient exposure.

4.2.15.3 Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation.

4.2.15.4 Radiologic technologists performing fluoroscopy as a localizing procedure shall be monitored by the supervising radiologist who is personally and immediately available.

4.2.16 Personnel Monitoring

4.2.16.1 All persons who are associated with the operation of an X-ray system are subject to the occupational exposure limits and the requirements for the determination of the doses which are stated in RHB 3.4. In addition, the following requirements are made:

4.2.16.1.1 When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is required, at least one such device shall be utilized as follows:

4.2.16.1.2 When an apron is worn, and one monitoring device is worn, the monitoring device shall be worn at the collar outside of the apron. If more than one monitoring device is worn, the devices shall be worn in accordance with RHB 3.12.2.

4.2.16.1.3 The dose to the whole body based on the maximum dose attributed to any one critical organ shall be recorded in the reports required by RHB 3.22. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

4.2.16.2 Exposure of a personnel monitoring device to falsely indicate a dose delivered to an individual is prohibited.

4.2.16.3 When an individual who has been given responsibility that involves occupational exposure to x-rays declares that she is pregnant, the employer must, at her request, provide her with an additional personnel monitoring device to be worn on the trunk underneath the leaded apron, when such apron is worn.

4.2.16.4 All employees who may be required to hold patients or films during x-ray examinations more than three times a quarter shall wear a personnel monitoring device.

4.2.17 X-ray Log. Each facility shall keep an x-ray log containing the patient's name, the type of examination, given by title as denoted on the technique chart, and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded. When the examination is performed using any type of fluoroscopy, the logbook shall include an estimate of the amount of time that fluoroscopy was performed or the number of times that the cumulative timer was reset. The fluoroscopy time is not required to be recorded for radiation therapy simulation units. Logs are not required for dental or veterinary x-ray equipment. X-ray log records shall be maintained for two years or until the next Department inspection, whichever is later.

4.2.18 Quality Assurance

4.2.18.1 Each registrant covered under RHB 4.5 through 4.12 must have "Equipment Performance Tests" performed on each x-ray unit. The registrant is required to meet the minimum performance criteria and test frequency. Facilities utilizing x-ray equipment for teaching or demonstration purposes only are exempt from this Part. Appendix F provides the required minimum performance criteria that must be tested. Equipment performance tests results must include numerical data. Items found to be non-compliant during such testing shall be corrected within sixty (60) days of receipt of the report. Records showing the test results and the correction of any non-compliant items found must be retained for five years. Equipment performance tests are to be performed:

4.2.18.1.1 At the time installation at all facilities, including veterinary facilities, or

4.2.18.1.2 Within thirty (30) days of installation, provided that the manufacturer's specified testing is performed at the time of installation and before patient use.

4.2.18.1.3 At the following specified intervals thereafter:

4.2.18.1.3.1 Dental x-ray equipment, including cephalometric units, shall be tested every four years alternating with Department inspections.

4.2.18.1.3.2 All medical x-ray equipment, including fluoroscopic, computerized tomography, and radiation therapy simulators, shall be tested annually. Self calibrating bone densitometry systems are exempt from this requirement. Mammography units shall meet the requirements of Part V.

4.2.18.1.3.3 Veterinary facilities are required to have equipment performance tests performed at the time of installation and at any time the Department deems necessary.

4.2.18.1.4 On any unit expected to remain at a facility for more than thirty (30) calendar days. If a unit is expected to remain at a facility for less than thirty (30) calendar days, the manufacturer's specified testing must be performed, at a minimum, prior to patient use. Mammography units shall meet the requirements of Part V.

4.2.18.2 The darkroom shall be light tight to the dark adapted eye and use proper safelighting such that a film exposed to x-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1 when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

4.2.18.3 If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast the grid shall:

4.2.18.3.1 Be positioned properly, i.e., tube side facing the right direction, and grid centered to the central ray,

4.2.18.3.2 If of the focused type, be of the proper focal distance for the SID's being used.

4.2.18.4 Each registrant shall establish a repeat analysis program. An analysis of repeats shall include, at a minimum, the overall repeat rate and the causes for the repeats. The repeat analysis shall be done monthly at facilities that produce less than 250 radiographs per month. Facilities that produce 250 or more radiographs per month shall do a repeat analysis weekly or after 1000 radiographs, whichever comes first. A different repeat analysis frequency may be granted upon application to the Department, provided that the requested frequency allows adequate monitoring, as determined by the Department. Registrants possessing dental or veterinary x-ray equipment are exempt from this requirement.

4.2.19 X-ray Film Processing. Each installation using a radiographic x-ray system and using analog imaging systems (radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

4.2.19.1 Manual Film Processing Systems

4.2.19.1.1 Processing tanks shall be constructed of mechanically rigid, corrosion resistant material.

4.2.19.1.2 A dedicated darkroom thermometer shall be used. The thermometer shall be used to adjust the film processing time according to solution temperature.

4.2.19.1.3 A dedicated darkroom timer with an adjustable preset function shall be used. The timer shall be used to adjust film processing time according to solution temperature.

4.2.19.1.4 Documentation shall be kept of the frequency at which film processing chemicals are changed. At a minimum, the interval as recommended by the chemical manufacturer shall be used.

4.2.19.1.5 Safelight.

4.2.19.1.5.1 The darkroom shall have a functional safelight.

4.2.19.1.5.2 The darkroom safelight shall be adequate for the film speed(s) and the darkroom operating procedures used to prevent fogging of unprocessed film.

4.2.19.1.6 The temperature of solutions in the tanks shall be maintained within the range of 60° F to 80° F (16° C to 27° C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time-temperature chart:

TIME TEMPERATURE CHART

Thermometer Reading (Degrees)	Minimum Developing Time (Minutes)
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°C	°F	
26.7	80	2
26.1	79	2
25.6	78	2 2
25.0	77	2 2
24.4	76	3
23.9	75	3
23.3	74	3 2
22.8	73	3 2
22.2	72	4
21.7	71	4
21.1	70	4 2
20.6	69	4 2
20.0	68	5
19.4	67	5
18.9	66	5 2
18.3	65	6
17.8	64	6 2
17.2	63	7
16.7	62	8
16.1	61	8 2
15.6	60	9 2

4.2.19.1.7 Radiographs shall not be "sight developed."

4.2.19.2 Automated Processors and Other Closed Processing Systems.

4.2.19.2.1 The temperature of film processing chemicals shall be appropriate for the type of film(s) being processed at the film transport speed selected.

4.2.19.2.2 The film processing chemicals used and their replenishing rate (if applicable) shall be appropriate for the film transport speed selected.

4.2.19.2.3 Safelight.

4.2.19.2.3.1 The darkroom shall have a functional safelight.

4.2.19.2.3.2 The darkroom safelight shall be adequate for the film speed(s) and the darkroom operating procedures used to prevent fogging of unprocessed film.

4.2.19.2.4 Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, the film shall be developed using the following chart:

Developer Temperature		Minimum Immersion Time *
°C	°F	Seconds

35	95	20
34	94	21
34	93	22
33	92	23
33	91	24
32	90	25

*Immersion time only, no crossover time included.

4.2.19.2.5 The specified developer temperature shall be immediately available.

4.2.19.2.6 The sensitometric performance of an automatic processor shall be equivalent to other operating processor models set up to meet the above developer temperature and immersion time specifications. This is determined by processing identically exposed film through each model and comparing the results.

4.2.19.2.7 Densitometric and sensitometric performance testing of the processor is required of facilities who process more than 250 films per week. Control limits shall be established for each parameter monitored. Provisions for correctable action shall be undertaken whenever the pre-established control limits are exceeded. Documentation of testing must be maintained for at least two years or until the next Department inspection, whichever is later. Registrants possessing dental or veterinary x-ray equipment are exempt from this requirement. Facilities processing more than 250 films per day are required to perform this testing on each day that examinations are performed before any clinical films are processed that day. Facilities processing less than 250 films per day, but more than 250 films per week, are required to perform this testing on a weekly basis, at a minimum. Facilities that operate 24 hours per day must perform the required testing once each day.

4.2.19.2.8 Records of processor maintenance shall be kept for at least two years or until the next Department inspection, whichever is later.

4.2.19.3 Other Requirements

4.2.19.3.1 Film pass boxes, if provided, shall be so constructed as to exclude light when film is placed in or removed from the boxes, and shall incorporate adequate shielding to prevent exposure of undeveloped film to stray radiation.

4.2.19.3.2 Darkrooms typically used by more than one individual shall be provided a positive method to prevent accidental entry while undeveloped films are being handled or processed.

4.2.19.3.3 Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

4.2.19.3.4 Film cassettes and intensifying screens shall be inspected in accordance with the facility's approved procedures and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality. Documentation of this periodic inspection and cleaning must be maintained for at least two years or until the next Department inspection, whichever is later.

4.2.19.3.5 Outdated x-ray film shall not be used for human diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base fog and speed.

4.2.19.3.6 Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

RHB 4.3 General Requirements for all Diagnostic X-ray Systems. All diagnostic x-ray systems shall meet the following requirements.

4.3.1 Warning Label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

4.3.2 Battery Charge Indicator. On battery powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

4.3.3 Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliRoentgen in 1 hour when the X-ray tube is operated at its maximum technique factors.

4.3.4 Radiation from Components Other than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliRoentgen in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed.

4.3.5 Beam Quality. The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an X-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made. For the purpose of this chart, specified dental systems shall be any dental intraoral unit manufactured before August 1, 1974 and on or after December 1, 1980.

TABLE I

Design Operating Range	Measured Potential	Specified Dental Systems	All other diagnostic
Below 51-----			
30	N/A	0.3	
40	N/A	0.4	
50	1.5	0.5	
51 to 70	51	1.5	1.2
60	1.5	1.3	
70	1.5	1.5	
Above 70	71	2.1	2.1
80	2.3	2.3	
90	2.5	2.5	
100	2.7	2.7	
110	3.0	3.0	
120	3.2	3.2	
130	3.5	3.5	
140	3.8	3.8	
150	4.1	4.1	

4.3.5.1 Beryllium window tubes shall have a minimum of 0.5 mm aluminum equivalent filtration permanently mounted in the useful beam.

4.3.5.2 For capacitor energy storage equipment, compliance with RHB 4.3.5 shall be determined with the maximum quantity of charge per exposure.

4.3.5.3 The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

4.3.5.4 All intraoral dental units manufactured after December 1, 1980 shall have at least 1.5 millimeters aluminum equivalent filtration permanently installed in the useful beam.

4.3.6 Filtration Controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by RHB 4.3.5 is in the useful beam for the given kVp which has been selected.

4.3.7 Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be on both the X-ray control and at or near tube housing assembly which has been selected.

4.3.8 Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the X-ray system.

4.3.9 Technique Indicators

4.3.9.1 The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

4.3.9.2 The requirement of RHB 4.3.9.1 may be met by permanently marking on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

4.3.9.3 The x-ray control shall provide visual indication of the production of x-rays.

4.3.9.4 X-ray systems utilizing arbitrary number or letter designators for kVp, time and milliAmperage shall be accompanied by a chart giving the value of physical factors for each arbitrary designator.

4.3.10 Focal Spot Indication. The focal spot shall be denoted in such a manner and area as to be easily seen on the tube housing.

4.3.11 Mechanical Timers. Use of mechanical timers is prohibited.

RHB 4.4 Shielding. Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations utilizing ionizing radiation for diagnostic or therapeutic purposes shall be reviewed by a Class III or Class IV vendor and submitted to the Department for review and approval. The registrant shall submit plans and a report, including any recommendations

and all basic assumptions used, from the vendor to the Department. In order for the Department to provide evaluation and approval, the information listed in Appendix B shall be submitted. The design considerations listed in Appendix C shall be followed. If design criteria in Appendix C cannot be followed, the registrant may offer alternative design criteria to the Department for approval as long as the same degree of safety is being met.

4.4.1 Each installation shall be provided with such primary barriers and secondary barriers as are necessary to assure compliance with RHB 3.3, RHB 3.4 and RHB 3.5. The requirement shall be deemed to be met if the thickness of such barriers is equivalent to the thickness as computed in accordance with Appendix D of the National Council of Radiation Protection and Measurements, Handbook 49 "Medical X-ray and Gamma-ray Protection for Energies up to 10 MEV", Handbook 35 "Dental X-ray Protection," or an equivalent reference.

4.4.2 The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in Part III of these regulations.

4.4.3 After installation of a radiation machine, the facility shall maintain for inspection by the Department:

4.4.3.1 The maximum rating of technique factors;

4.4.3.2 A scale drawing of the room in which a stationary radiation machine system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. The drawing shall include the type and thickness of materials, or lead equivalency of each protective barrier.

4.4.3.3 A copy of the shielding plan, required by RHB 4.4 and approved by the Department.

4.4.3.4 A copy of the area survey, if required by RHB 4.4.7.

4.4.4 Within 30 days after construction and installation are complete, the facility shall ensure that "as-built" drawings are submitted to the Department. The drawings must indicate the composition of the walls, floor, ceiling, windows and doors. The drawings must also indicate the placement of the x-ray equipment, including the table, control, and vertical cassette holder, if provided, as well as the location and composition of the film bin, if present.

4.4.5 X-ray equipment shall not be used before a shielding plan for the unit has been approved by the Department.

4.4.6 A shielding plan shall also be required when a facility replaces an existing x-ray machine control or generator or when operating procedures at the facility change to an extent so as to render the original shielding plan inaccurate. A shielding plan may not be required upon replacement of a x-ray machine control or generator if the facility can document to the Department's satisfaction, that the original shielding plan remains adequate for that installation.

4.4.7 The registrant shall have a radiation area survey performed by a Class IX vendor, registered with the Department, within thirty days after installation of the x-ray equipment. A survey shall be required for all installations of x-ray equipment where the approved shielding plan indicates that ordinary building materials, such as sheetrock, concrete and brick are not sufficient for radiation protection purposes. The Department may determine that a survey is not required for some installations. The

Department shall make a determination as to whether or not a survey is required, and shall notify the facility, in writing, of its determination. The survey shall be submitted to the Department for review, and shall include a scale drawing of the room, indicating the composition of the walls, floor, ceiling, windows, and doors, and the placement of the x-ray equipment, including the table, control, and vertical cassette holder, if provided. The location and composition of the film bin shall also be included. The survey shall include an evaluation of the adequacy of each protective barrier, the operator's location, and the film storage area, if appropriate.

4.4.8 All wall, floor, and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of 2.13 meters above the floor.

4.4.9 Secondary barriers shall be provided in all wall, floor and ceiling areas not having primary barriers.

4.4.10 The operator's station at the control shall be behind a protective barrier either in a separate room, in a protected booth, or behind a shield which will intercept the useful beam and any radiation which has been scattered only once.

4.4.11 Mobile and portable x-ray systems used in conjunction with a permanently installed cassette holder shall be considered a stationary radiographic system and shall meet the requirements for such an installation.

RHB 4.5 Dental Radiographic Installations. In addition to the provisions of RHB 4.3 and 4.4, the requirements of RHB 4.5 apply to x-ray equipment and associated facilities used for dental radiography.

4.5.1 Source to Skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-to-skin distance, to not less than eighteen (18) centimeters.

4.5.2 Field Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray field such that:

4.5.2.1 The x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters.

4.5.2.2 An open ended PID shall be used, and shall provide the same degree of protection as the housing. Pointed PIDs shall not be used.

4.5.2.3 The operator shall position the end of the PID as close as practicable to the skin of the patient.

4.5.3 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

4.5.3.1 It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

4.5.3.2 Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "Zero".

4.5.3.3 Timer reproducibility. The average exposure period (\bar{T}) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed: $\bar{T} \geq 5 (T_{max} - T_{min})$.

4.5.4 X-ray Control.

4.5.4.1 An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (1/2) second or less.

4.5.4.2 Each x-ray control shall be located in such a way as to meet the following requirements:

4.5.4.2.1 Stationary x-ray systems installed after July 1, 1993, shall have the x-ray control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure; and

4.5.4.2.2 For stationary x-ray systems without a protected area and installed before July 1, 1993, the exposure switch shall be such that the operator shall stand at least six feet away from the tube housing and out of the direct beam.

4.5.4.2.3 The operator shall be able to view the patient during all exams in which x-rays are produced. For systems installed before July 1, 1993, the exposure switch and viewing position shall be no less than six feet away from the x-ray tube head.

4.5.4.2.4 For mobile and portable x-ray systems, the exposure switch shall meet the requirements of 4.5.4.2.2.

4.5.4.2.5 The x-ray control shall provide visual and/or audible indication observable at or from the operator's protected position whenever x-rays are produced. The visual and/or audible signal shall indicate that the exposure has terminated.

4.5.5 Exposure Reproducibility. The coefficient of variation shall not exceed 0.05 when all selectable technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made at identical technique factors, the value of the average exposure (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $\bar{E} \geq 5 (E_{max} - E_{min})$.

4.5.6 Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the maximum rating, the average ratios of exposure to the indicated milliAmpere-seconds product obtained at any two tube current settings shall not differ by more than 0.10 times their sum: $[X1 - X2] < 0.10 (X1 + X2)$ where $X1$ and $X2$ are the average mR/mAs values obtained at each of the two tube current settings.

4.5.7 Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by the manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed 10% of the indicated value.

4.5.8 kVp limitations. Dental x-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

4.5.9 Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control and at or near the tube housing which has been selected.

4.5.10 Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted so that the tube housing assembly will remain stable during an exposure unless the tube housing movement is a designed function of the X-ray system.

4.5.11 Structural Shielding.

4.5.11.1 Dental rooms containing x-ray machines shall be provided with primary barriers for all areas struck by the useful beam.

4.5.11.2 When dental x-ray units are installed in adjacent rooms or areas, protective barriers shall be provided between the rooms or areas.

4.5.11.3 Pass throughs. Pass throughs between adjacent areas shall be securely interlocked.

4.5.12 Operating Procedures.

4.5.12.1 Neither the dentist nor his assistant shall hold patients or films during exposure, nor shall any individual be regularly used for this service.

4.5.12.2 The tube housing and the PID shall not be hand-held during an exposure.

4.5.12.3 Dental fluoroscopy without image intensification shall not be used.

4.5.12.4 Each patient undergoing dental radiography shall be draped with a protective apron of not less than 0.25 millimeter lead equivalent to cover the gonadal area unless the patient refuses.

4.5.12.5 Only persons required for the radiographic procedure shall be in the radiographic room during exposures.

RHB 4.6 Extraoral Dental Radiographic Installations.

4.6.1 Cephalometric Installations

4.6.1.1 All provisions of RHB 4.7 apply.

4.6.1.2 The radiographic field shall be restricted to the area of the image receptor.

4.6.2 Panoramic Installations

4.6.2.1 All provisions of RHB 4.5 apply, except 4.5.1 and 4.5.2.1.

4.6.3 Other Installations. The Department may impose by rule, regulation, or order any requirements deemed appropriate or necessary to ensure appropriate and proper operation of any extraoral dental radiographic installation that is not a cephalometric or panoramic unit.

RHB 4.7 Medical Radiographic Systems. The requirements of this Part apply to x-ray equipment and associated facilities used for radiography with stationary radiographic systems other than intraoral dental, fluoroscopic, computed tomography (CT), mammography or veterinary medical systems.

4.7.1 Stationary General Purpose Units. In addition to the other provisions of this part, all stationary general purpose units must also meet the following requirements:

4.7.1.1 Means shall be provided for independent stepless adjustment of at least two dimensions of the x-ray field.

4.7.1.2 Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.7.1.3 Means shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

4.7.1.4 The beam limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

4.7.1.5 Indication of field size dimensions and SID's used shall be specified in inches and/or centimeters on the collimator. The indications on the collimator shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent (2%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

4.7.1.6 The beam limiting device shall be provided with SID scales that reflect the actual SID(s) used for radiographic procedures.

4.7.1.7 Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID.

4.7.2 X-ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

4.7.3 Special Purpose X-ray Systems. In addition to the other provisions of this Part, all special purpose x-ray systems shall also meet the following requirements:

4.7.3.1 Means shall be provided to limit the x-ray field in the plane of the image receptor such that the x-ray field does not exceed each dimension of the image receptor by more than 2% of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.7.3.2 Means shall be provided to align the center of the X-ray field with the center of the image receptor to within two percent (2%) of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of

the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.

4.7.3.3 The above RHB 4.7.3.1 and 4.7.3.2 may be met with a system that meets the requirements for a general purpose X-ray system as specified in Part RHB 4.7.3, above or, when alignment means are also provided, may be met with either:

4.7.3.3.1 An assortment of removable, fixed aperture, beam limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

4.7.3.3.2 A beam limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

4.7.4 Radiation Exposure Control Devices.

4.7.4.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

4.7.4.2 X-ray Control.

4.7.4.2.1 An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time ("deadman" switch) except for exposures of one-half (1/2) second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

4.7.4.2.2 Stationary x-ray systems shall have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

4.7.4.2.3 Mobile and portable x-ray systems which are:

4.7.4.2.3.1 Used for greater than 1 week in same location, i.e., a room or suite, shall meet the requirements of 4.7.4.2.2;

4.7.4.2.3.2 Used for greater than 1 hour and less than 1 week at the same location, i.e., a room or suite, shall meet the requirement of 4.7.4.2.3.1 or be provided with a 6.5 feet high protective barrier which is placed at least 6 feet from the tube housing assembly and at least 6 feet from the patient; or

4.7.4.2.3.3 Used to make an exposure(s) of a patient at the use location shall meet the requirement of 4.7.4.2.3.1 or be provided with a method of x-ray control which will permit the operator to be at least 6 feet from the tube housing assembly during an exposure.

4.7.4.2.4 The X-ray control shall provide visual indication observable at or from the operator protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

4.7.4.2.5 The X-ray control shall be so placed that the operator can view the patient during any exposure and still stand in a protected area.

4.7.4.2.6 Automatic Exposure Controls. When an automatic exposure control is provided:

4.7.4.2.6.1 Indication shall be made on the control panel when this mode of operation is selected;

4.7.4.2.6.2 If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to 2 pulses;

4.7.4.2.6.3 The minimum exposure time for all equipment other than that specified in 4.7.4.2.6.2 shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver 5 mAs, whichever is greater;

4.7.4.2.6.4 Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kW per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

4.7.4.2.6.5 A visible signal shall indicate when an exposure has been terminated at the limits required by 4.7.4.2.6.4, and manual resetting shall be required before further automatically timed exposures can be made.

4.7.4.2.7 Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure period (\bar{T}) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed: $\bar{T} \geq 5 (T_{max} - T_{min})$.

4.7.5 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 when all selectable technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $\bar{E} \geq 5 (E_{max} - E_{min})$.

4.7.6 Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the X-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliRoentgen per hour at five (5) centimeters from any accessible surface of the diagnostic source assembly, with the beam limiting device fully open.

4.7.7 Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10% of the indicated value.

4.7.8 Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

4.7.8.1 Equipment having independent selection of x-ray tube current (mA). The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any tube current settings shall not differ by more than 0.10 times their sum. This is: $[X1-X2] < 0.10 (X1+X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two tube current settings.

4.7.8.2 Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any two mAs selector settings shall not differ by more than 0.10 times their sum. This is : $[X1-X2] < 0.10 (X1+X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two mAs selector settings.

4.7.8.3 Measuring Compliance. Determination of compliance shall be based on 4 exposures, at each of the two settings. The two settings may include any two focal spot sizes provided that neither focal spot size is equal to or less than 0.45 millimeter, in which case the two settings shall be restricted to the same focal spot size. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

4.7.9 Light Localization.

4.7.9.1 When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

4.7.9.2 Exemptions to RHB 4.7.9.1 shall be granted if the registrant demonstrates to the Department that their equipment is unable to meet these regulations, and the Department determines that patient safety or image quality is not compromised.

4.7.10 Certified Systems. In addition to the requirements of these rules, the registrant shall not make, nor cause to be made, any modification of components or installations of components certified pursuant to US Food and Drug Administration Regulation 21 CFR 1020 "Performance Standards for Ionizing Radiation Emitting Products" in any manner that could cause the installations or the components to fail to meet the requirements of the applicable parts of the standards specified in 21 CFR 1020, except where a variance has been granted by the Director, Center for Devices and Radiological Health, Food and Drug Administration.

4.7.11 Maintenance Schedule. On all equipment containing components certified pursuant to US Food and Drug Administration Regulation CFR 1020 "Performance Standards for Ionizing Radiation Emitting Products" the registrant shall perform, or cause to be performed, the schedule of maintenance provided by the manufacturer pursuant to 21 CFR 1020.30(h)(1)(ii). A log book of such maintenance shall be maintained for inspection by the Department.

4.7.12 SID Indication. Means shall be provided to indicate the SID. SIDs shall be indicated in inches and/or centimeters, and shall be indicated to within 2 percent.

4.7.13 Positive Beam Limitation. For units having an operable positive beam limitation (PBL) system, the following requirements must be met:

4.7.13.1 Neither the length nor width of the x-ray field shall differ from the corresponding image receptor dimensions by more than 3 percent of the SID; and

4.7.13.2 The sum of the length and width differences, without regard to sign, shall not exceed 4 percent of the SID.

4.7.13.3 The positive beam limitation system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters by 5 centimeters.

4.7.13.4 The positive beam limitation system shall be designed such that if a change in image receptor does not cause automatic return to positive beam limitation function as described in 4.7.10.1 and 4.7.10.2, then any change of image receptor size or SID must cause the automatic return.

4.7.13.5 PBL compliance shall be determined with the beam axis perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

4.7.14 The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device has been properly used or if evidence of collimation has been shown on at least three sides or three corners of the film, (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

4.7.15 Minimum Field Size. The minimum field size at an SID of 100 cm shall be equal to or less than 5 centimeters by 5 centimeters.

RHB 4.8 Mobile Radiographic Equipment.

4.8.1 All provisions of RHB 4.7.4 through 4.7.15 apply, except 4.7.13.

4.8.2 Means shall be provided for independent stepless adjustment of at least two dimensions of the x-ray field.

4.8.3 Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.8.4 Means shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

4.8.5 If provided, the beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

4.8.6 If collimator indications are provided, the indications shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent (2%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

4.8.7 Means shall be provided to measure SIDs, and shall be accurate to within 2%.

4.8.8 Mobile and portable x-ray systems which are used continually in a single location for a period of greater than one week shall be considered a stationary radiographic system and shall meet the requirements of RHB 4.4.

4.8.9 Mobile and portable x-ray systems which are used at multiple locations shall be provided with an adequate protective barrier or protective apron for the operator and with a method of control which will permit the operator to be at least 12 feet from the tube head and the nearest edge of the useful beam during exposures.

4.8.10 Personnel monitoring shall be required for all operators of mobile and portable x-ray systems.

4.8.11 Tube stands. A tube stand or other mechanical support shall be used for portable x-ray systems so that the x-ray tube housing assembly need not be hand-held during exposures.

4.8.12 All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters.

RHB 4.9 Fluoroscopic X-ray Systems. All fluoroscopic x-ray systems shall be image intensified, and meet the following requirements. The requirements of this part apply to all stationary, portable, mobile, and C-arm type fluoroscopes.

4.9.1 Source-to-Skin Distance (SSD). The SSD shall not be less than:

4.9.1.1 38 centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974.

4.9.1.2 35.5 centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974.

4.9.1.3 30 centimeters on all mobile and portable fluoroscopes, and

4.9.1.4 20 centimeters for mobile fluoroscopes used for specific surgical procedures. The written safety procedures as required by RHB 4.2.4 must provide precautionary measures to be taken during the use of this type of fluoroscope. If removable, the appropriate spacer shall be replaced after the specific surgical procedure application is complete.

4.9.2 Limitation of Useful Beam.

4.9.2.1 Primary Barrier

4.9.2.1.1 The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

4.9.2.1.2 The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

4.9.2.2 X-ray field. Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID. In addition:

4.9.2.2.1 Means shall be provided to permit further limitation of the x-ray field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a

visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;

4.9.2.2.2 All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of 5 centimeters by 5 centimeters or less.

4.9.2.2.3 For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.9.2.2.4 Compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. For rectangular x-ray fields used with circular image reception, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

4.9.2.2.5 For uncertified image-intensified fluoroscopic equipment with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters table top to the film plane distance.

4.9.2.3 Spot film devices which are certified components shall meet the following additional requirements.

4.9.2.3.1 Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option.

4.9.2.3.2 Spot film field size. Neither the length nor the width of the x-ray field in the spot film plane shall exceed the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

4.9.2.3.3 It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters.

4.9.2.3.4 The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID.

4.9.2.3.5 On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

4.9.3 Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any

exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

4.9.4 Exposure Rate Limits. Entrance Exposure Rate Allowable Limits.

4.9.4.1 For equipment manufactured prior to May 19, 1995:

4.9.4.1.1 Equipment with automatic exposure rate control. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 Roentgens (2.58 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

4.9.4.1.1.1 During recording of fluoroscopic images, or

4.9.4.1.1.2 When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 Roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level control shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

4.9.4.1.2 Equipment without automatic exposure rate control. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 Roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

4.9.4.1.2.1 During recording of fluoroscopic images, or

4.9.4.1.2.2 When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

4.9.4.2 For equipment manufactured after May 19, 1995:

4.9.4.2.1 Equipment with automatic exposure rate control. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 Roentgens (2.58 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

4.9.4.2.1.1 During recording of fluoroscopic images, or

4.9.4.2.1.2 When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 20 Roentgens (5.16 mC/kg) per minute at the point where the center of the useful beam enters the patient when the high level control is activated. Special means of activation of high level control shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

4.9.4.2.2 Equipment without automatic exposure control. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 Roentgens (1.29 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

4.9.4.2.2.1 During recording of fluoroscopic images, or

4.9.4.2.2.2 When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 20 Roentgens (5.16 mC/kg) per minute at the point where the center of the useful beam enters the patient when the high level control is activated. Special means of activation of high level control shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

4.9.4.3 Compliance with 4.9.4.1 and 4.9.4.2 shall be determined as follows:

4.9.4.3.1 If the source is below the x-ray table, the exposure rate shall be measured 1 centimeter above the tabletop or cradle.

4.9.4.3.2 If the source is above the x-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

4.9.4.3.3 In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

4.9.4.3.4 For a variable SID C-arm type of fluoroscope the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the end of the beam-limiting device or spacer positioned as close as possible to the point of measurement.

4.9.4.3.5 In a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.

4.9.4.3.6 Periodic measurement of entrance exposure rate shall be performed for both maximum and typical values in each mode used clinically annually, and after any maintenance of the system which might affect the exposure rate. Results of the most recent measurements in each mode used clinically shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and be included in the records required in RHB 4.2.18.1. The measurement results shall be stated in Roentgens per minute and include the technique factors used in determining such results. The name of the person performing the measurements and the date the measurements were performed shall be included in the results.

4.9.4.3.7 Conditions of measurement of maximum entrance exposure rate are as follows:

4.9.4.3.7.1 The measurement shall be made under the conditions that satisfy the requirements of RHB 4.9.4.3.

4.9.4.3.7.2 The kVp, mA, and other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate.

4.9.4.3.7.3 The x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum output of that system.

4.9.4.3.7.4 Testing shall be performed in each mode used clinically.

4.9.4.3.8 Conditions of measurement of typical entrance exposure rate are as follows:

4.9.4.3.8.1 The measurement shall be made under the conditions that satisfy the requirements of RHB 4.9.4.3.

4.9.4.3.8.2 The kVp and mA shall be typical of clinical use of the x-ray system.

4.9.4.3.8.3 The x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliAmpere and/or kiloVoltage typical of the use of the x-ray system.

4.9.4.3.8.4 Testing shall be performed in each mode used clinically.

4.9.5 Barrier Transmitted Radiation Rate Limits. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, shall not exceed 2 milliRoentgen (0.516 uC/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each Roentgen per minute of entrance exposure rate.

4.9.5.1 Measuring Compliance of Barrier Transmission.

4.9.5.1.1 The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

4.9.5.1.2 If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

4.9.5.1.3 If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

4.9.5.1.4 Compression devices shall be removed from the useful beam during the measurement.

4.9.6 Indication of Potential and Current. During fluoroscopy and cinefluoroscopy the kV and mA shall be continuously indicated.

4.9.7 Fluoroscopic Timer.

4.9.7.1 Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.

4.9.7.2 A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

4.9.8 Control of Scattered Radiation.

4.9.8.1 Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

4.9.8.2 Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

4.9.8.2.1 Is at least 120 centimeters from the center of the useful beam, or

4.9.8.2.2 The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in RHB 4.2.11.2.

4.9.8.3 The Department may grant exemptions to RHB 4.9.8.2.2 where a sterile field will not permit the use of the normal protective barriers. Automatic exemptions will be granted for fluoroscopic procedures listed in Appendix E.

4.9.9 Spot-Filming Procedures. Fluoroscopic x-ray systems equipped with a spot-film device must meet the following requirements for spot-film procedures:

4.9.9.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

4.9.9.2 Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure period (\bar{T}) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed: $\bar{T} \geq 5(T_{max} - T_{min})$.

4.9.9.3 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 when all selectable technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $\bar{E} \geq 5(E_{max} - E_{min})$.

4.9.10 Mobile and Portable fluoroscopic x-ray systems which are used for greater than one week in the same location, i.e., a room or suite, shall be considered as a fixed installation, and shall meet all the requirements of RHB 4.4.

4.9.11 Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of 4.9.2, 4.9.4, 4.9.5, and 4.9.7 provided that:

4.9.11.1 Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays, unless the procedure requires the presence of other individuals.

4.9.11.2 Systems which do not meet the requirements of RHB 4.9.7 are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

4.9.12 Fluoroscopic Quality Assurance. In addition to the requirements of RHB 4.2.18, the fluoroscopic image resolution shall be tested as part of the quality assurance program. This shall be performed at least annually.

4.9.13 Vertical Fluoroscopic Imaging Systems.

4.9.13.1 SSD. The SSD shall not be less than 38 centimeters.

4.9.13.2 Limitation of Useful Beam. All provisions of 4.9.2 apply.

4.9.13.3 Entrance Exposure Rates. All provisions of 4.9.4 apply.

4.9.13.4 Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

4.9.13.5 Indication of Potential and Current. During fluoroscopy and cinefluorography the kV and mA shall be continuously indicated.

4.9.13.6 Fluoroscopic Timer.

4.9.13.6.1 Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting.

4.9.13.6.2 A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

4.9.13.7 Operators shall remain in a protected area during exposures, or shall be protected by aprons of not less than 0.25 mm lead equivalent material.

4.9.13.8 Spot-Filming Procedures. Fluoroscopic x-ray systems equipped with a spot-film device must meet the following requirements for spot-film procedures:

4.9.13.8.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

4.9.13.8.2 Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure period (T) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed: $T \geq 5(T_{\text{max}} - T_{\text{min}})$.

4.9.13.8.3 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $E \geq 5(E_{\max} - E_{\min})$.

RHB 4.10 Bone Densitometry Systems. The requirements of this part apply to all stationary, portable, and mobile x-ray bone densitometry systems.

4.10.1 Registration. All provisions of RHB 2.3 and 2.4 apply.

4.10.2 Shielding.

4.10.2.1 Stationary units. The registrant shall submit to the Department for review and approval a shielding plan, as required by RHB 4.4. The shielding plan may be, but is not required to be, prepared by a vendor registered with the Department to perform such service. In lieu of a shielding plan, the Department may accept a radiation area survey, performed by a vendor registered with the Department to perform such service. The shielding plan shall be submitted for review and approval prior to use of the bone densitometry unit. The radiation area survey shall be performed and submitted to the Department within thirty days of initial use of the unit.

4.10.2.2 Mobile and portable units are exempt from 4.10.2.1.

4.10.2.3 The Department may require the registrant to submit a shielding plan prepared by a vendor registered with the Department to perform such service.

4.10.3 Location. The bone densitometry system shall be placed in a controlled area. The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during examination.

4.10.4 Administrative Requirements.

4.10.4.1 Personnel Monitoring. All provisions of RHB 3.12 and 3.22 apply.

4.10.4.2 Posting Requirements. All provisions of RHB 3.16.1, 4.2.9, and 9.2.1 apply.

4.10.4.3 Operating Procedures. All provisions of RHB 4.2.4 apply.

4.10.4.4 Operators. All provisions of RHB 4.2.3 apply.

4.10.4.5 The operator shall advise the patient, prior to the exam, that the bone densitometry examination is a type of x-ray.

RHB 4.11 Computed Tomography (CT) X-ray Systems.

4.11.1 Equipment Requirements.

4.11.1.1 Tomographic Plane Indication and Alignment.

4.11.1.1.1 For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

4.11.1.1.2 For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. The reference plane can be offset from the location of the tomographic planes.

4.11.1.1.3 If a device using a light source is used to satisfy 4.11.1.1.1 or 4.11.1.1.2, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

4.11.1.2 Indication of CT Conditions of Operation. The CT x-ray system shall be designed to be used during a scan or a scan sequence are indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

4.11.1.3 Initiation of Operation.

4.11.1.3.1 The x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

4.11.1.3.2 Means shall be provided to require operator initiation of each individual scan or series of scans.

4.11.1.3.3 All emergency buttons/switches shall be clearly labeled as to their functions.

4.11.1.4 Termination of Exposure.

4.11.1.4.1 Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

4.11.1.4.2 A visible signal shall indicate when the x-ray exposure has been terminated through the means required by 4.11.1.4.1.

4.11.1.4.3 The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under x-ray system control, of greater than 0.5 second duration. Termination of the x-ray exposure shall necessitate resetting of the CT conditions of operation prior to initiation of another scan.

4.11.1.5 Extraneous Radiation. The system shall perform such that the radiation produced adjacent to the tube housing assembly, including the tube port, during periods of time that scans are not being performed does not exceed the levels permitted by RHB 4.3.3.

4.11.1.6 Additional Requirements Applicable to CT X-ray Systems Containing a Gantry Manufactured After September 3, 1985.

4.11.1.6.1 The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

4.11.1.6.2 If the x-ray production period is less than 0.5 second, the indication of x-ray production shall be actuated for at least 0.5 second. Indicators at or near the gantry shall be discernable from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

4.11.1.6.3 The deviation of indicated scan increment versus actual increment shall not exceed to within 1 millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment can be taken anywhere along this travel.

4.11.2 Facility Design Requirements.

4.11.2.1 The control panel and x-ray control must be mounted in a permanently protected area outside the computed tomography room. The operator is required to remain in that protected area during the entire exposure.

4.11.2.2 Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

4.11.2.3 After the effective date of these regulations, facilities designed with an open area in the control room that leads to the gantry shall mark this open area conspicuously indicating not to stand or sit in this area during x-ray exposures.

4.11.2.4 Units installed after the effective date of these regulations shall have the outside door(s) of the gantry room interlocked so that a scan cannot be initiated if the door is not completely closed.

4.11.2.5 Viewing Systems.

4.11.2.5.1 Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

4.11.2.5.2 When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

4.11.3 Dose Measurements and Spot Checks.

4.11.3.1 Dose Measurement.

4.11.3.1.1 Dose measurements of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a Class IX Vendor.

4.11.3.1.2 Dose measurements of a CT x-ray system shall be performed at intervals specified by a Class IX Vendor and after any change or replacement of components which, in the opinion of the vendor could cause a significant change in the radiation output.

4.11.3.1.3 Measurements of the radiation output of the CT x-ray system shall be performed with a calibrated dosimetry system. The dosimetry system shall have been calibrated or intercompared with a calibrated chamber within the preceding 2 years. The calibration of such system shall be traceable to a national standard.

4.11.3.1.4 Calibration procedures shall be in writing. Records of calibration performed shall be maintained for inspection by the Department.

4.11.3.2 Spot Checks.

4.11.3.2.1 Spot check procedures shall be developed by a Class IX vendor who specializes in diagnostic radiological physics.

4.11.3.2.2 All spot checks shall be included in the calibration required by RHB 4.11.3.1, and otherwise at time intervals and system conditions specified by a Class IX Vendor.

4.11.3.2.3 Spot checks shall include acquisition of images obtained with the phantoms using the same processing mode and CT conditions of operation as are used to perform dose measurements required by RHB 4.11.3.1. The images shall be retained, until a new dose measurement is performed, in two forms as follows:

4.11.3.2.3.1 Photographic copies of the images obtained from the image display view; and

4.11.3.2.3.2 Images stored in digital form of the most recent spot check on a storage medium compatible with the CT x-ray system.

4.11.4 Operating Procedures. The operator's manual, radiation area surveys, and current equipment performance testing of the system shall be available at the control console.

4.11.5 Ancillary personnel who are not necessary for the safety of the patient shall not be present in the area of the CT unit while exposures are being made.

4.11.6 CT units used in radiation therapy treatment planning are exempt from the requirements of RHB 4.11.3.1. All other provisions of RHB 4.11 apply.

RHB 4.12 Veterinary Radiographic Systems.

4.12.1 Administrative Requirements. All provisions of RHB 4.2 apply, except 4.2.3, 4.2.9, 4.2.12, and 4.2.13.

4.12.2 Radiation Protection. All provisions of RHB 4.2.11 apply, except 4.2.11.3.

4.12.3 Holding of Patients and Films. All provisions of RHB 4.2.14 apply. In addition:

4.12.3.1 Each veterinary facility shall have lead gloves and aprons available in the area of the x-ray unit.

4.12.3.2 Each veterinary facility that holds patients shall provide personnel monitoring devices. If the human holder's hands are in or near the primary beam, then ring badges shall also be provided.

4.12.4 General Requirements. All provisions of RHB 4.3 and 4.4 apply.

4.12.5 Means shall be provided for independent stepless adjustment of at least two dimensions of the x-ray field.

4.12.6 Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

4.12.7 Means shall be provided for visually defining the perimeter of the X-ray field. The total misalignment of the edges of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

4.12.8 The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted.

4.12.9 Indication of field size dimensions and SID's used shall be specified in inches and/or centimeters on the collimator. The indications on the collimator shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent (2%) of the SID when the beam axis is perpendicular to the plane of the image receptor.

4.12.10 The beam-limiting device shall be provided with SID scales that reflect the actual SID(s) used for radiographic procedures.

4.12.10.1 Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2% of the SID.

4.12.10.2 Diaphragms or cones when provided for collimating the useful beam to the area of clinical interest shall meet the requirements of RHB 4.7.2.

4.12.10.3 Minimum Field Size. The minimum field size at an SID of 100 cm shall be equal to or less than 5 cm X 5 cm.

4.12.11 Radiation Exposure Control Devices.

4.12.11.1 Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer has been set to a zero or off position if either position is provided.

4.12.11.2 X-ray Control.

4.12.11.2.1 An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time ("deadman" switch) except for exposures of one-half (1/2) second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

4.12.11.2.2 The X-ray control shall provide visual indication observable at or from the operator protected position whenever X-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

4.12.11.2.3 Timer Reproducibility. With a timer setting of 0.5 second or less, the average exposure period (\bar{T}) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer test are performed: $\bar{T} \geq 5 (T_{max} - T_{min})$.

4.12.12 Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.05 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure (\bar{E}) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}): $\bar{E} \geq 5 (E_{max} - E_{min})$.

4.12.13 Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the X-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliRoentgen per hour at five (5) centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

4.12.14 Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10% of the indicated value.

4.12.15 Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

4.12.15.1 Equipment having independent selection of x-ray tube current (mA). The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any tube current settings shall not differ by more than 0.10 times their sum. This is: $[X1-X2] < 0.10 (X1+X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two tube current settings.

4.12.15.2 Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios of exposure to the indicated milliAmpere-seconds product (C/kg/mAs (or mR/mAs)) obtained at any two mAs selector settings shall not differ by more than 0.10 times their sum. This is: $[X1-X2] < 0.10 (X1+X2)$; where X1 and X2 are the average C/kg/mAs (or mR/mAs) values obtained at any two mAs selector settings.

4.12.15.3 Measuring compliance. Determination of compliance shall be based on 4 exposures, at each of the two settings. These two settings may include any two focal spot sizes provided that neither focal spot size is equal to or less than 0.45 millimeter, in which case the two settings shall be restricted to the same focal spot size. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

4.12.16 Light Localization.

4.12.16.1 When a light field is used to define the x-ray field, it shall provide an average illumination of not less than 15 footcandles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field.

4.12.16.2 The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. the contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of 1 millimeter in diameter.

4.12.16.3 Exemptions to RHB 4.12.16.1 and 4.12.16.2 shall be granted if the registrant demonstrates to the Department that their equipment is unable to meet these regulations.

4.12.17 SID Indication. Means shall be provided to indicate the SID. SIDs shall be indicated in inches and/or centimeters, and shall be indicated to within 2 percent.

4.12.18 Fluoroscopic X-ray Systems. Veterinary fluoroscopic x-ray systems shall meet the following requirements:

4.12.18.1 Limitation of Useful Beam.

4.12.18.1.1 Primary Barrier.

4.12.18.1.1.1 The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

4.12.18.1.1.2 The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

4.12.18.1.2 X-ray Field. The x-ray field produced by non-image intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. This requirement applies to field size for both fluoroscopic procedures and spot filming procedures. In addition:

4.12.18.1.2.1 Means shall be provided for stepless adjustment of the field size;

4.12.18.1.2.2 The minimum field size at the greatest SID shall be equal to or less than 5 centimeters by 5 centimeters.

4.12.18.1.2.3 For image-intensified fluoroscopic equipment, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID. In addition, means shall be provided to permit further limitation of the field.

4.12.18.2 Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means shall be provided to permit completion of any single exposure of the series in process.

4.12.18.3 Barrier Transmitted Radiation Rate Limits.

4.12.18.3.1 The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliRoentgen (0.516 uC/kg) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each Roentgen per minute of entrance exposure rate.

4.12.18.3.2 Measuring Compliance of Barrier Transmission.

4.12.18.3.2.1 The exposure rate due to transmission through the protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

4.12.18.3.2.2 If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

4.12.18.3.2.3 If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

4.12.18.4 Indication of Potential and Current. During fluoroscopy the kV and mA shall be continuously indicated.

4.12.18.5 Mobile Fluoroscopes. In addition to the other requirements of this Part, mobile fluoroscopes shall provide intensified imaging.

4.12.18.6 Control of Scattered Radiation.

4.12.18.6.1 Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

4.12.18.6.2 Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to unattenuated scattered radiation emanating from above the tabletop unless that individual:

4.12.18.6.2.1 Is at least 120 centimeters from the center of the useful beam, or

4.12.18.6.2.2 The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in RHB 4.12.3.1.

4.12.19 X-ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

4.12.20 Veterinary Computed Tomography X-ray Systems - All provisions of RHB 4.11.1 through 4.11.1.5 apply.

4.12.20.1 Facility Design Requirements - All provisions of RHB 4.11.2 apply except 4.11.2.2

4.12.20.2 Operating Procedures. All provisions of RHB 4.11.5 apply.

4.12.21 Operator Requirements. The registrant shall assure that all x-ray machines under his control are operated only by individuals adequately instructed in safe operating procedures and competent in the safe use of the equipment.

4.12.21.1 The registrant shall require persons operating registered equipment and associate equipment to receive, at a minimum, instruction in the following areas:

4.12.21.1.1 Radiation Protection. Training in radiation protection shall include protective clothing; patient holding; time, distance, and shielding; and radiation protection standards.

4.12.21.1.2 Darkroom Techniques. Training in darkroom techniques shall include developing chemicals; film protection; cassettes; and screens.

4.12.21.1.3 Machine Safety. Training in machine safety shall include machine functions; safety procedures; and recognizing problems.

4.12.21.1.4 General Operating Procedures. Training in general operating procedures shall include patient positioning for x-ray exams; radiographic techniques; use of personnel monitoring devices; and quality assurance procedures.

4.12.21.2 Instruction required by 4.12.21.1 shall begin within 30 days after employment. Training shall be provided for each type of exam that the operator will be required to perform at that facility. The registrant shall maintain a record of all training for each operator. Such records shall be made available for Departmental inspection.